

By: Lucio

S.B. No. 1383

A BILL TO BE ENTITLED

AN ACT

relating to the licensing and regulation of medical laboratory science professionals; providing penalties; imposing fees.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. Subtitle M, Title 3, Occupations Code, is amended by adding Chapter 703 to read as follows:

CHAPTER 703. MEDICAL LABORATORY SCIENCE PROFESSIONALS

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 703.001. SHORT TITLE. This chapter may be cited as the Medical Laboratory Science Practice Act.

Sec. 703.002. PUBLIC POLICY; LEGISLATIVE PURPOSE. (a) The legislature declares as a policy of this state that:

(1) the practice of medical laboratory science by health care professionals affects the public health, safety, and welfare and is subject to control and regulation in the public interest; and

(2) medical laboratories and medical laboratory science professionals provide essential services to health care professionals by furnishing vital information that may be used in the diagnosis, prevention, and treatment of diseases or impairments and the assessment of human health.

(b) The purpose of this chapter is to ensure better protection of the public health by:

(1) requiring minimum qualifications for medical

1 laboratory science professionals; and

2 (2) ensuring that medical laboratory tests are
3 performed with the highest degree of professional competency by
4 individuals engaged in providing the services in this state.

5 Sec. 703.003. DEFINITIONS. In this chapter:

6 (1) "Advisory committee" means the Medical Laboratory
7 Science Advisory Committee.

8 (2) "Categorical medical laboratory scientist" means
9 an individual licensed under this chapter to perform medical
10 laboratory scientist services in one major practice area of a
11 laboratory under the supervision, control, and responsibility of a
12 laboratory director.

13 (3) "CLIA" means the federal Clinical Laboratory
14 Improvement Amendments of 1988 (42 C.F.R. Part 493).

15 (4) "Commission" means the Texas Commission of
16 Licensing and Regulation.

17 (5) "Department" means the Texas Department of
18 Licensing and Regulation.

19 (6) "Executive director" means the executive director
20 of the department.

21 (7) "Independent technical judgment" means the
22 performance of clinical laboratory tests and assumption of
23 responsibility for determining the validity of clinical laboratory
24 test results without intervention by or the direct supervision of a
25 health care professional.

26 (8) "Laboratory director" means a person who meets the
27 requirements of a laboratory director under CLIA.

1 (9) "Medical laboratory" means a facility in which a
2 medical laboratory test is performed for diagnosis, prevention, or
3 treatment of disease or impairment or assessment of human health.

4 (10) "Medical laboratory scientist" means an
5 individual who uses independent technical judgment in the
6 performance of tests and procedures under the supervision, control,
7 and responsibility of a laboratory director.

8 (11) "Medical laboratory scientist services" means:

9 (A) the use of independent technical judgment in
10 the performance of medical laboratory tests;

11 (B) the establishment and implementation of
12 protocols, quality assessment, method development and selection,
13 equipment selection and maintenance, and all activities related to
14 the pre-analytic, analytic, and post-analytic phases of medical
15 laboratory testing under the supervision, control, and
16 responsibility of a laboratory director; and

17 (C) the direction, supervision, consultation,
18 education, and performance of research functions related to medical
19 laboratory testing.

20 (12) "Medical laboratory technician" means an
21 individual licensed under this chapter to perform medical
22 laboratory technician services.

23 (13) "Medical laboratory technician services" means
24 the performance of medical laboratory tests in accordance with
25 established and approved protocols that require the limited
26 exercise of independent technical judgment and are performed under
27 the supervision of a medical laboratory scientist, laboratory

supervisor, or laboratory director.

(14) "Medical laboratory test" means a microbiological, serological, chemical, biological, hematological, immunological, immunochemical, immunoassay, cytochemical, or genetic test or procedure performed on material derived from or existing in a human body that provides information for the diagnosis, prevention, or monitoring of a disease or impairment or assessment of a medical condition. The term includes the pre-analytic, analytic, and post-analytic phases of testing.

(15) "Point-of-care testing" means analytical patient testing activities provided at a health care facility but performed outside the central medical laboratory facilities that do not require permanent dedicated space, including testing using analytical instruments at a temporary patient care location.

(16) "Practice of medical laboratory science" means practice by an individual who manages, supervises, educates, consults, researches, or performs medical laboratory testing or technical procedures in a medical laboratory. The term does not include an activity that constitutes the practice of medicine or the activities of a person performing only clerical duties or other duties not directly related to the performance of medical laboratory testing.

(17) "Waived test" means a simple laboratory examination or procedure that, under a federal interpretation of CLIA, employs a simple and accurate methodology that renders the likelihood of erroneous results negligible or poses no reasonable risk of harm to the patient if performed incorrectly.

1 Sec. 703.004. EXEMPTIONS. This chapter does not apply to:

2 (1) a physician licensed to practice medicine in this
3 state;

4 (2) an individual licensed under another law of this
5 state and engaged in health care services within the scope of the
6 license holder's licensed practice;

7 (3) an individual engaged in the practice of medical
8 laboratory science in the employ of the federal government or a
9 federal bureau, division, or agency and in the discharge of the
10 employee's official duties;

11 (4) an individual engaged in the practice of medical
12 laboratory science and engaged exclusively in research, provided
13 that the results of an examination performed are not used in health
14 maintenance, diagnosis, or treatment of disease;

15 (5) an intern, student, or trainee enrolled in a
16 medical laboratory science education program, provided that:

17 (A) the activities constitute a part of a planned
18 course in the program;

19 (B) the individual is designated by title as an
20 intern, student, or trainee; and

21 (C) the individual works directly under an
22 individual licensed by this state to practice medical laboratory
23 science or an individual exempt from this chapter under Subdivision
24 (4);

25 (6) an individual solely performing waived or
26 provider-performed microscopy tests under CLIA;

27 (7) an individual performing point-of-care testing

categorized under CLIA as moderate complexity in an acute care facility, if the facility complies with the following requirements:

(A) in the laboratory, a laboratory director is responsible for:

(i) designing and providing or supervising the training programs for the point-of-care testing personnel;

(ii) supervising and monitoring the quality assurance and quality control activities of the testing site;

(iii) assisting in the selection of technology;

(iv) reviewing the results of proficiency testing and recommending corrective action, if necessary; and

(v) monitoring the continued competency of the testing personnel; and

(B) processes are in place at the facility and are acceptable to the department to ensure and document the continued competency of the point-of-care testing personnel;

(8) an individual solely performing histopathology testing or performing or interpreting the results of molecular testing on histological specimens, as described by CLIA;

(9) an individual solely performing or interpreting cytology testing, including the performance or interpretation of molecular testing on cytological specimens, as described by CLIA, provided that this chapter may not be construed as a limitation on the scope of work permitted under CLIA for qualified cytotechnologists;

(10) a medical laboratory assistant who performs

1 non-testing pre-analytical duties, including processing specimens,
2 accessioning, loading specimens into analyzers, or preparing
3 specimens for referral testing;

4 (11) an individual solely performing or interpreting
5 histocompatibility testing for transplantation services;

6 (12) an individual solely performing or interpreting
7 testing by mass spectrometry, provided the individual has a
8 bachelor's degree in a chemical science and meets the CLIA
9 requirements for testing personnel performing high complexity
10 testing; or

11 (13) an individual performing testing on
12 plasmapheresis specimens in a laboratory regulated by the federal
13 Food and Drug Administration.

14 Sec. 703.005. APPLICATION OF SUNSET ACT. The Medical
15 Laboratory Science Advisory Committee is subject to Chapter 325,
16 Government Code (Texas Sunset Act). Unless continued in existence
17 as provided by that chapter, the advisory committee is abolished
18 and this chapter expires September 1, 2027.

19 SUBCHAPTER B. POWERS AND DUTIES

20 Sec. 703.051. RULES. (a) The commission shall adopt rules
21 to administer this chapter and as necessary to protect the public
22 health, safety, and welfare, including rules on:

23 (1) the qualifications to obtain a license under each
24 category of medical laboratory science professional;

25 (2) the renewal of a license;

26 (3) standards of professional conduct;

27 (4) authorization or approval of nationally

recognized and validated certification examinations for medical laboratory science professionals; and

(5) criteria for the continuing education of medical laboratory science professionals as required for license renewal.

(b) The commission by rule shall prescribe the activities that may be performed by each category of license holder under this chapter.

(c) The commission by rule may exempt a medical laboratory science professional who is employed by a certification agency approved by the executive director from licensing and continuing education fees.

(d) This chapter may not be construed as providing the department, commission, or executive director authority to:

(1) regulate the activities of a physician who is directing a clinical laboratory; or

(2) establish by rule an academic, educational, or testing requirement that is not expressly prescribed or required by this chapter.

Sec. 703.052. FEES. The commission by rule shall establish and collect reasonable and necessary fees in amounts sufficient to:

(1) cover the costs of administering this chapter; and

(2) provide reasonable funding for medical laboratory personnel education.

Sec. 703.053. DEPARTMENT POWERS AND DUTIES. (a) The department may authorize disbursements necessary to implement this chapter, including disbursements for office expenses, equipment costs, and other necessary facilities.

1 (b) The department may examine any criminal conviction or
2 guilty plea of an applicant for issuance or renewal of a license,
3 including by obtaining any criminal history record information
4 authorized by law.

5 Sec. 703.054. PERSONNEL. The department may employ
6 personnel necessary to administer this chapter.

7 Sec. 703.055. REGISTRY OF LICENSE HOLDERS. (a) The
8 department shall maintain a registry of the name and address of each
9 individual licensed under this chapter and each individual whose
10 license has been suspended or revoked.

11 (b) The department shall post the registry on the
12 department's Internet website and make copies of the registry
13 available to the public on request.

14 Sec. 703.056. CONSUMER INTEREST INFORMATION. (a) The
15 department shall prepare information of consumer interest
16 describing:

17 (1) the functions performed by the department under
18 this chapter; and

19 (2) the rights of a consumer affected by this chapter.

20 (b) The information must describe the procedure by which a
21 consumer complaint is filed with and resolved by the department.

22 (c) The department shall make the information available to
23 the public.

24 SUBCHAPTER C. MEDICAL LABORATORY SCIENCE ADVISORY COMMITTEE

25 Sec. 703.101. ADVISORY COMMITTEE. (a) The Medical
26 Laboratory Science Advisory Committee is an advisory body to the
27 department and executive director.

1 (b) The advisory committee consists of nine members
2 appointed by the department as follows:

3 (1) three members who are medical laboratory science
4 professionals who are not physicians, at least one of whom is a
5 medical laboratory scientist and at least one of whom is not a
6 laboratory director;

7 (2) three members who are pathologists certified by
8 The American Board of Pathology, the American Osteopathic Board of
9 Pathology, or another certification board the department
10 determines has certification requirements at least as stringent as
11 those of The American Board of Pathology or the American
12 Osteopathic Board of Pathology;

13 (3) one member who is a physician and is not a
14 laboratory director or pathologist;

15 (4) one member who is a medical laboratory science
16 educator and is not a physician; and

17 (5) one public member.

18 (c) The department may make appointments to the advisory
19 committee from lists submitted by organizations of medical
20 laboratory science professionals and organizations of physician
21 pathologists.

22 (d) Chapter 2110, Government Code, does not apply to the
23 advisory committee.

24 Sec. 703.102. TERMS; VACANCIES. (a) Members serve
25 staggered six-year terms and until their successors are appointed
26 and qualified.

27 (b) A vacancy shall be filled for the remainder of the

1 unexpired term in the same manner as an original appointment.

2 (c) A member may not serve more than two consecutive terms.

3 Sec. 703.103. PUBLIC MEMBER ELIGIBILITY. A member who
4 represents the public may not be:

5 (1) an officer, director, or employee of an individual
6 regulated under this chapter;

7 (2) an individual required to register as a lobbyist
8 under Chapter 305, Government Code; or

9 (3) an individual related to an individual described
10 by Subdivision (1) or (2) within the second degree by affinity or
11 consanguinity.

12 Sec. 703.104. COMPENSATION; REIMBURSEMENT. A member of the
13 advisory committee serves without compensation. If authorized by
14 the department, an advisory committee member is entitled to
15 reimbursement for actual and necessary expenses incurred in
16 performing the functions of the advisory committee, subject to the
17 General Appropriations Act.

18 Sec. 703.105. MEETINGS. The advisory committee shall meet
19 annually and may meet at other times at the call of the executive
20 director.

21 Sec. 703.106. ADVISORY COMMITTEE DUTIES. The advisory
22 committee shall provide advice and recommendations to the
23 department and executive director on technical matters relevant to
24 the administration and enforcement of this chapter, including
25 certification agency approval, licensing standards and
26 qualifications, renewal requirements, standards of professional
27 conduct, and continuing education requirements.

SUBCHAPTER D. LICENSE REQUIREMENTS

Sec. 703.151. LICENSE REQUIRED. Except as provided by Section 703.004, an individual may not perform or offer to perform medical laboratory tests or represent that the individual is a medical laboratory science professional unless the individual holds an appropriate license issued under this chapter.

Sec. 703.152. APPLICATION REQUIREMENTS. (a) An applicant for a license under this chapter must:

(1) submit to the department a completed application on a form prescribed by the executive director;

(2) submit to the department any other information required by rule;

(3) demonstrate to the satisfaction of the department the qualifications required by this chapter and by rule;

(4) demonstrate the applicant's honesty, trustworthiness, and integrity; and

(5) pay the application fee.

(b) The department shall issue the appropriate license to each individual who meets the qualifications required by this chapter and by rule.

(c) The department may conduct an examination of any criminal conviction of an applicant, including obtaining any criminal history record information authorized by law.

(d) Criminal history record information obtained by the department may not be released or disclosed to any person except on court order or with the written consent of the applicant who is the subject of the criminal history record information.

1 Sec. 703.153. MEDICAL LABORATORY SCIENTIST. An applicant
2 for a medical laboratory scientist license must:

3 (1) hold at least a bachelor's degree from a regionally
4 accredited college or university;

5 (2) have successfully completed the medical
6 laboratory experience or training required by rule;

7 (3) be certified by a nationally recognized
8 certification organization approved by the executive director;

9 (4) pay the application fee and license fee; and

10 (5) comply with any other requirements established by
11 rule.

12 Sec. 703.154. CATEGORICAL MEDICAL LABORATORY SCIENTIST. An
13 applicant for a categorical medical laboratory scientist license
14 must:

15 (1) hold at least a bachelor's degree from a regionally
16 accredited college or university;

17 (2) have successfully completed the medical
18 laboratory experience or training required by rule;

19 (3) be certified by a nationally recognized
20 certification organization approved by the executive director;

21 (4) pay the application fee and license fee; and

22 (5) comply with any other requirements established by
23 rule.

24 Sec. 703.155. MEDICAL LABORATORY TECHNICIAN. (a) An
25 applicant for a medical laboratory technician license must:

26 (1) hold at least an associate degree from a
27 regionally accredited college or university;

1 (2) have successfully completed the medical
2 laboratory experience or training required by rule;

3 (3) be certified by a nationally recognized
4 certification organization approved by the executive director;

5 (4) pay the application fee and license fee; and

6 (5) comply with any other requirements established by
7 rule.

8 (b) The department shall accept as satisfying the
9 requirement of Subsection (a)(1) evidence that the applicant has:

10 (1) successfully completed a course in procedures for
11 a military laboratory of not less than 50 weeks in length; and

12 (2) served as a medical laboratory specialist or
13 laboratory technician in the military.

14 Sec. 703.156. TEMPORARY LICENSE. (a) The commission by
15 rule may establish a procedure for issuance of temporary licenses
16 to individuals under this chapter who intend to engage in the
17 practice of medical laboratory science in this state for a limited
18 period not to exceed six months.

19 (b) Unless otherwise noted on the license, a temporary
20 license is valid for not more than six months after the date of
21 issuance and may be renewed once.

22 Sec. 703.157. PROVISIONAL LICENSE. The department may
23 issue a provisional license under this chapter to an applicant who
24 holds a license in another state, submits a proper application, and
25 pays the required fees if the department determines that the
26 applicant is licensed in a state in which the requirements for
27 issuance of the license are at least as stringent as the

requirements under this chapter and by rule. A provisional license under this section is valid for not more than 90 days.

Sec. 703.158. LICENSE TERM AND RENEWAL. (a) A license issued under this chapter expires on the second anniversary of the date of issuance. The commission by rule may adopt a system under which licenses expire on various dates during the year.

(b) A license holder may renew the license by paying the required renewal fee and:

(1) successfully completing at least 10 hours each year of continuing education courses, clinics, lectures, training programs, seminars, or other programs related to medical laboratory practice that are approved or accepted by the executive director; or

(2) successfully completing recertification by a national certifying organization recognized by the executive director that mandates at least 10 hours each year of continuing education for recertification.

(c) The commission by rule may require additional evidence of competency to practice medical laboratory science as reasonably appropriate as a prerequisite to the renewal of any license under this chapter if the requirements are:

(1) uniformly applied;

(2) reasonably related to the measurement of qualification, performance, or competence; and

(3) desirable and necessary for the protection of the public health.

SUBCHAPTER E. LICENSE DENIAL AND DISCIPLINARY ACTION

Sec. 703.201. GROUNDS FOR DISCIPLINARY ACTION. The executive director may refuse to issue or renew, revoke, or suspend a license, place on probation, censure, or reprimand a license holder, or take any other disciplinary action, including the imposition of a civil penalty under Section 703.202 or the imposition of an administrative penalty under Section 703.204, the department considers appropriate for:

(1) a material misstatement in furnishing information to the department;

(2) a violation or negligent or intentional disregard of this chapter or a rule adopted under this chapter;

(3) a conviction for any crime under the laws of the United States or any state of the United States that is a felony or a misdemeanor, an essential element of which is dishonesty, or of any crime that is directly related to the practice of the profession;

(4) a misrepresentation made to obtain a license;

(5) a violation of any standard of professional conduct adopted by the commission;

(6) dishonorable, unethical, or unprofessional conduct of a character likely to deceive, defraud, or harm the public;

(7) the provision of professional services while mentally incompetent or under the influence of alcohol, a narcotic, or a controlled dangerous substance that is in excess of therapeutic amounts or without valid medical indication;

(8) directly or indirectly contracting to perform

medical laboratory tests in a manner that offers or implies an offer of rebate, fee-splitting inducements or arrangements, or other remuneration;

(9) aiding or assisting another individual in violating any provision of this chapter or a rule adopted under this chapter; or

(10) a misrepresentation with regard to the existence or category of license or other certification or professional qualification held in connection with any employment application.

Sec. 703.202. CIVIL PENALTY. (a) A person who violates this chapter or a rule adopted under this chapter is liable to this state for a civil penalty of not more than \$500 for each violation.

(b) The amount of the penalty shall be based on:

(1) the seriousness of the violation;

(2) the history of previous violations;

(3) the amount necessary to deter a future violation;

and

(4) any other matter that justice may require.

(c) The attorney general may sue to collect a civil penalty under this section. In the suit the attorney general may recover, on behalf of the state, the reasonable expenses incurred in obtaining the penalty, including investigation and court costs, reasonable attorney's fees, witness fees, and other expenses.

Sec. 703.203. HEARINGS; ADMINISTRATIVE PROCEDURE. (a) If the department proposes to deny a license or take disciplinary action against a license holder, the license holder is entitled to a hearing.

1 (b) The proceedings relating to a license denial and
2 disciplinary action by the department under this chapter are
3 governed by Chapter 2001, Government Code. A hearing under this
4 chapter shall be conducted by the State Office of Administrative
5 Hearings.

6 Sec. 703.204. ADMINISTRATIVE PENALTY. (a) The commission
7 or executive director may impose an administrative penalty on an
8 individual licensed under this chapter who violates this chapter or
9 a rule or order adopted under this chapter.

10 (b) The amount of the penalty may not exceed \$500. Each day
11 a violation continues or occurs is a separate violation for the
12 purpose of imposing a penalty. The amount shall be based on:

13 (1) the seriousness of the violation, including the
14 nature, circumstances, extent, and gravity of the violation;

15 (2) the economic harm caused by the violation;

16 (3) the history of previous violations;

17 (4) the amount necessary to deter a future violation;

18 (5) efforts to correct the violation; and

19 (6) any other matter that justice may require.

20 (c) The individual may stay enforcement during the time the
21 order is under judicial review if the individual pays the penalty to
22 the court clerk or files a supersedeas bond with the court in the
23 amount of the penalty. An individual who cannot afford to pay the
24 penalty or file the bond may stay enforcement by filing an affidavit
25 in the manner required by the Texas Rules of Civil Procedure for a
26 party who cannot afford to file security for costs, except that the
27 department may contest the affidavit as provided by those rules.

1 (d) The attorney general may sue to collect the penalty.

2 (e) A proceeding to impose an administrative penalty is
3 subject to Chapter 2001, Government Code.

4 SUBCHAPTER F. TRANSITIONAL LICENSING

5 Sec. 703.251. TEMPORARY PROVISION; LICENSING. (a) This
6 subchapter expires September 1, 2021. The department may not issue
7 a license under this subchapter after August 31, 2019.

8 (b) The department shall issue a license to a qualified
9 applicant under this subchapter who:

10 (1) submits to the department the information required
11 by rule, including, as applicable:

12 (A) the job description of the medical laboratory
13 position the applicant most recently held and a sworn statement by
14 the applicant's employer attesting to the applicant's job
15 description; or

16 (B) proof that the applicant is certified by a
17 nationally recognized certification agency approved by the
18 executive director; and

19 (2) pays the application and licensing fee.

20 Sec. 703.252. MEDICAL LABORATORY SCIENTIST. To qualify for
21 a license under this subchapter as a medical laboratory scientist,
22 an applicant must:

23 (1) be currently certified to perform medical
24 laboratory scientist services by a certification agency approved by
25 the executive director; or

26 (2) have performed the duties of a medical laboratory
27 scientist for at least three years during the five years preceding

1 the date of application.

2 Sec. 703.253. CATEGORICAL MEDICAL LABORATORY SCIENTIST. To
3 qualify for a license under this subchapter as a categorical
4 medical laboratory scientist, an applicant must:

5 (1) be currently certified to perform medical
6 laboratory scientist services in one major practice area by a
7 certification agency approved by the executive director; or

8 (2) have performed the duties of a categorical medical
9 laboratory scientist for at least three years during the five years
10 preceding the date of application.

11 Sec. 703.254. MEDICAL LABORATORY TECHNICIAN. To qualify
12 for a license under this subchapter as a medical laboratory
13 technician, an applicant must:

14 (1) be currently certified to perform medical
15 laboratory technician services by a certification agency approved
16 by the executive director; or

17 (2) have performed the duties of a medical laboratory
18 technician for at least three years during the five years preceding
19 the date of application.

20 Sec. 703.255. EFFECT OF LICENSE. The holder of a license
21 issued under this subchapter is entitled to practice to the same
22 extent as the holder of a license under Subchapter D.

23 Sec. 703.256. RENEWAL. A license issued under this
24 subchapter expires on the second anniversary of the date of
25 issuance. Notwithstanding the qualifications for an initial
26 license under Section 703.153, 703.154, or 703.155, the license may
27 be renewed as a license under Section 703.158.

1 SECTION 2. As soon as possible after the effective date of
2 this Act, the Texas Department of Licensing and Regulation shall
3 appoint the members of the Medical Laboratory Science Advisory
4 Committee in accordance with Chapter 703, Occupations Code, as
5 added by this Act. In making the initial appointments, the
6 department shall designate:

7 (1) three members for terms expiring February 1, 2017;

8 (2) three members for terms expiring February 1, 2019;

9 and

10 (3) three members for terms expiring February 1, 2021.

11 SECTION 3. The Texas Commission of Licensing and Regulation
12 and the executive director of the Texas Department of Licensing and
13 Regulation, as appropriate, shall adopt the rules, standards,
14 procedures, and fees necessary to implement Chapter 703,
15 Occupations Code, as added by this Act, not later than August 31,
16 2016.

17 SECTION 4. Notwithstanding Chapter 703, Occupations Code,
18 as added by this Act, an individual engaged in the practice of
19 medical laboratory science is not required to hold a license under
20 that chapter to engage in the practice of medical laboratory
21 science before September 1, 2017.

22 SECTION 5. This Act takes effect September 1, 2015.